

§ 158.2160 Microbial pesticides product performance data requirements.

Product performance data must be developed for all microbial pesticides. However, the Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

§ 158.2170 Experimental use permit data requirements—microbial pesticides.

(a) *For all microbial pesticides.* (1) The following § 158.2171 through § 158.2174 identify the data requirements that are required to support experimental use permits for microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) For general information on the data requirement tables, see § 158.2110(a)(2)–(4).

(b) *Additional data requirements for genetically modified microbial pesticides.*

Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the “new” traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section.

(b) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; All = All of the above.

(c) *Table.* The table in this paragraph shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Test guideline No.	Data requirement	All use pat- terns	Test substance		Test notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product identity	R	MP	EP.	1, 2 3
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	
885.1250	Deposition of a sample in a nationally recognized culture collection.	R	TGAI	TGAI	
885.1300	Discussion of formation of uninten- tional ingredients.	R	TGAI and MP	TGAI and EP	2
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2, 4
885.1500	Certification of limits	R	MP	EP.	